

REMARKS

In view of the above amendments and following remarks, reconsideration and further examination are requested.

By the current Amendment, claims 2, 3 and 5 have been amended so as to delete therefrom the reference characters "VS", "VC" and "L".

Claims 2 and 6 were rejected under 35 USC § 102(b) as being anticipated by Tanaka et al.; claim 5 was objected to as being dependent upon a rejected base claim, but was indicated to be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims; and claims 3 and 7 were allowed. The indication of allowable subject matter is greatly appreciated; however, claim 5 has not been rewritten in independent form because it is respectfully submitted that claim 2 is allowable over Tanaka et al.

In order to discuss the rejection of claim 2, a telephonic interview was conducted with Examiner Schell on June 19, 2007. The courtesies extended by Examiner Schell in granting and conducting this interview are greatly appreciated.

During this interview, Applicants' undersigned representative explained by it is believed that claim 2 is not anticipated by Tanaka et al. Specifically, it was expressed to Examiner Schell that the limitation of the final "wherein" clause in claim 2 is not believed to be taught or suggested by Tanaka et al. because volume (VS) as claimed includes the volume occupied by the front plug member. It was also expressed that Fig. 6 of Tanaka et al. corresponds to the positional relationship represented by this "wherein" clause. Thus, when corresponding volumes are measured in Fig. 6 of Tanaka et al., the volume corresponding to claimed volume (VS) has a length of about 18mm, and the volume 7 corresponding to claimed volume (VC) has a length of about 15mm, whereby this "wherein" clause cannot be read on Tanaka et al.

Examiner Schell was in agreement, and stated that the 35 USC § 102(b) rejection of claim 2 based on Tanaka et al. would not be maintained; however, Examiner Schell indicated that a 35 USC § 103(a) rejection would be given. Specifically, Examiner Schell indicated that to change

the proportions/volumes of medications within the syringe based on different needs of individual patients would have been an obvious matter of design choice.

One having ordinary skill in the art may have found it obvious to modify proportions of the components in the first and second chambers based upon individual needs of patients; however, for the following reasons it is respectfully submitted that the specific ratio as claimed is for a purpose other than for meeting the individual needs of patients.

As for a dual-chamber type prefilled syringe, the second chamber is designed so as to have a volume based on an amount of medicine required by a patient, and the first chamber is designed to have a volume as large as required to allow for an operation of mixing a first component (contained in the first chamber) with a second component (contained in the second chamber). Specifically, these volumes are determined by a dimension of the front plug member and a position where it is fitted, a length of the bypass and a position where it is formed, and a dimension of the middle plug member and a position where it is fitted.

The front plug member is moved toward the leading end (the first end) of the cylindrical body since the first chamber has its volume increased by the second component flowing thereinto when the second component is transferred from the second chamber to the first chamber via the bypass. While this second component is being transferred from the second chamber to the first chamber, if the front plug member comes to be out of the leading end of the cylindrical body due to the foregoing movement, there is caused a problem in that the second component partly flows into the needle-attaching portion.

In order to avoid this problem, it is necessary to fit the front plug member at a position sufficiently separate from the leading end of the cylindrical body, so that the front plug member does not come to be out of the leading end of the cylindrical body even if all the second component is transferred to the first chamber. Conventionally, the syringe has been designed based on this idea. For example, as with Tanaka et al., the volume from the leading end of the cylindrical body to the rear end of the front plug member is designed so as to become larger than the volume of the second component.

More specifically, the position where the front plug member is fitted varies depending on an amount of medicine (volume of the second component) required by the patient, but nobody thought to vary a volume ratio, and as a result, it would not have been obvious for one having ordinary skill in the art to make the dual-chamber type prefilled syringe so as to have the volume ratio as recited in claim 2. That is, it would not have been obvious to make the volume from the leading end of the cylindrical body to the rear end of the front plug member be not more than the volume of the second component when the rear end of the middle plug member has reached the rear end portion of the bypass.

According to the syringe of Tanaka et al., the front plug member is fitted at a position sufficiently separate from the leading end of the cylindrical body, which can assuredly prevent the likelihood that the second component partly flows into the needle-attaching portion. However, this syringe results in the cylindrical body being unnecessarily long, and also requires that the front plug member has to be pushed for a longer distance, which in turn requires a longer plunger rod. This causes a problem in that it is not easy for an operator, particularly one having a small hand, to perform a communication and mixing operation of the two components. This causes an additional problem in that if the cylindrical body is too long, it is not easy to stabilize the leading end of the injection needle when administering the medicine.

The present inventors have carefully observed the behavior of the second component when it is transferred from the second chamber to the first chamber via the bypass, and as a result have found that if the syringe is designed so as to have the above-mentioned volume ratio, it is possible to inhibit the second component from flowing into the needle-attaching portion, and have thus arrived at the present invention.

Provision of the syringe as recited in claim 2 offers effects that the syringe of Tanaka et al. cannot present. In this regard, the syringe as recited in claim 2 offers the following effects of being able

- 1) to prevent the cylindrical body from becoming unnecessarily long,
- 2) to confine the length of the plunger rod to be short, and

3) to readily perform a communication and mixing operation of the first and second components, as well as an administering operation of these mixed components.

Thus, even though one may have found it obvious to vary the respective volumes of the first and second components based on individual needs of patients, because the specific ratio as claimed is for solving a specific problem, and because an explanation has not been provided as to why the claimed ratio would necessarily result from considering individual needs of patients, it is respectfully submitted that a prima facie case of obviousness cannot be established for claim 2 based on Tanaka et al.

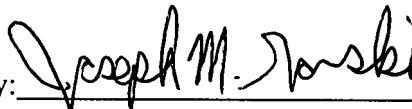
Thus, claims 2, 5 and 6 are allowable along with claims 3 and 7.

In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early Notice of Allowance is earnestly solicited.

If after reviewing this Amendment, the Examiner believes that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the Applicants' undersigned representative by telephone to resolve such issues.

Respectfully submitted,

Masahiko KATO et al.

By: 
Joseph M. Gorski
Registration No. 46,500
Attorney for Applicants

JMG/nka
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
July 9, 2007